

Protocol Title:

1. The use or disclosure of Protected Health Information (PHI) involves no more than a minimal risk to the privacy of individuals. Explain why below, followed by completion of the PHI and source sections.

Explain:

Check the PHI that apply to your study:

- | | |
|--|--|
| <input type="checkbox"/> Name | <input type="checkbox"/> Account numbers |
| <input type="checkbox"/> Geographic information smaller than a state | <input type="checkbox"/> Certificate of license numbers |
| <input type="checkbox"/> Elements of dates including birth date, admission date, date of death, and all ages >89 | <input type="checkbox"/> Vehicle identifiers & serial nos. including license plate |
| <input type="checkbox"/> Telephone numbers | <input type="checkbox"/> Device identifiers & serial numbers |
| <input type="checkbox"/> Fax numbers | <input type="checkbox"/> URLs |
| <input type="checkbox"/> E-mail addresses | <input type="checkbox"/> Internet Protocol (IP) address nos. |
| <input type="checkbox"/> Social Security Number | <input type="checkbox"/> Biometric identifiers, incl. Finger and voice prints |
| <input type="checkbox"/> Medical Records numbers | <input type="checkbox"/> Full face photographic images & comparable images |
| <input type="checkbox"/> Health plan beneficiary numbers | <input type="checkbox"/> Any other unique identifying number, characteristic, hospital/medical records (in and out pt) |

Check the sources of PHI you will use:

- | | |
|--|---|
| <input type="checkbox"/> Patient Charts | <input type="checkbox"/> Blood Draws |
| <input type="checkbox"/> Lab, Pathology and/or Radiology Results | <input type="checkbox"/> MRI Scans, X-Rays, etc. |
| <input type="checkbox"/> Mental Health Records | <input type="checkbox"/> Billing Records or Code |
| <input type="checkbox"/> Physician/Clinic Records | <input type="checkbox"/> PHI previously collected for research purposes |
| <input type="checkbox"/> Questionnaires/Interviews | |
| <input type="checkbox"/> Data containing no health information* | |

**If this is the only source of data, the research does not include PHI; therefore, HIPAA regulations do not apply to this research study, and you do not need to complete this form.*

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access to it.

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is:

4. Describe the procedure used to destroy all the data collected during the study (electronic, paper, audio/visual, photography, other) – OR – the identifiers collected during the study will not be destroyed because:

5. The research could not be practicably conducted without the waiver because:

6. The research could not be practicably conducted without access to and use of PHI because:

7. HIPAA regulations require reasonable efforts to limit protected health information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request. Explain why PHI obtained for this study is the minimum information needed to meet the research objectives.

The information listed in the Waiver Application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria.

As Principal Investigator, I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to re-use this information for other purposes or disclose the information to other individuals or entity(s), I will seek approval by the IRB.

Principal Investigator – Print Name

Principal Investigator Signature

Date

Note: HIPAA regulations allow the IRB to waive use of authorization form if ALL of the criteria listed above are met.